IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

NATERA, INC., Plaintiff, v. NEOGENOMICS LABORATORIES, INC., Defendant.	C.A. No. 1:23-CV-629

DEFENDANT NEOGENOMICS LABORATORIES, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO STAY

FILED UNDER SEAL
[EXPEDITED TREATMENT REQUESTED]

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I. INTRODUCTION

Pursuant to Federal Rule of Civil Procedure 62(d), NeoGenomics Laboratories, Inc. ("NeoGenomics") respectfully requests an immediate stay of the Court's preliminary injunction of December 27, 2023 pending resolution of its appeal to the Federal Circuit and, in any event, an expedited resolution of this motion. NeoGenomics requests a response to this motion by January 2, 2024 in view of the harms identified below.

A stay pending appeal is warranted because NeoGenomics has at the very least raised substantial appeal questions regarding the merit of the Order that, especially taken together, establish a strong likelihood of success on appeal and each do so on their own. Much of the supporting evidence and reasoning is in NeoGenomics's prior submissions and was presented at the preliminary injunction hearing, but some key points specific to the Court's Opinion and Order are set forth below.

NeoGenomics intends to ask the Federal Circuit to expedite its appeal, which could result in a decision within 90 days. Given that Natera did not even ***assert*** the '035 Patent for seven months from when it issued in December 2022—even though it asserted other patents against RaDaR at that time—and that RaDaR has been commercially available for years, the short requested stay is warranted.

On the merits, the Court rejected NeoGenomics's showing that there was a substantial obviousness question for jury resolution solely on the ground that combining prior art to perform the methods described in the '035 Patent would have required overcoming some unique "challenges." But the law does not hold that a combination is

obvious only if a prospective user would encounter *no* obstacles in combining existing methods. Moreover, the Court overlooked that *Natera itself* (and its experts) have repeatedly claimed that applying existing DNA sequencing techniques to cell-free DNA ("cfDNA") would have been obvious to a person of ordinary skill in the art. Natera's about-face in this litigation at the very least raises a substantial question as to validity that a jury could reasonably resolve in favor of NeoGenomics.

In addition, the Court did not address the merits of the invalidity of the '035 Patent due to a written description violation. The Court stated there was insufficient explanation of this defense and that NeoGenomics did not focus this defense on the '035 Patent. However, NeoGenomics's submission as explicated at the hearing—and the Court's own engagement with the issue at the hearing—provided more than ample basis to raise a substantial question on this invalidity issue for the '035 Patent that is inconsistent with the grant of a preliminary injunction.

On infringement, the Court failed to address the principal issue in dispute between the parties: Whether the second step of claim 1 must be performed only after the completion of the first step (as one would intuit), or whether instead the first and second step can be completed simultaneously. Proper consideration and resolution of that issue would at least raise a substantial question of whether NeoGenomics's RaDaR product infringes the '035 Patent.

As to irreparable harm and public interest, the Court did not address critical evidence showing that Natera would not lose material market share to NeoGenomics, that

tumor-informed and tumor-naïve products in fact compete with each other, and that RaDaR is more sensitive so that it applies to cancer indications that Natera's product is not suited to address. The evidence shows that RaDaR's superior sensitivity allows patients and scientists to help save lives from types of cancer that Natera's Signatera product simply cannot address. The public interest in the availability of RaDaR's superior sensitivity to detect different cancers is profound. All this evidence raises substantial appeal issues.

The other factors strongly favor a stay pending appeal. Absent a stay, NeoGenomics will be irreparably harmed, as even Natera's expert stated, putting at risk its [redacted] investment in RaDaR and inflicting a more than $400 million dollar single-day stock loss. The fact that NeoGenomics has other products that can keep it afloat in the interim is no reason to discount the serious and irreparable harm it undisputedly will face from the preliminary injunction. And given the minimal harm to Natera for an interim stay pending appeal, the hardships tilt in favor of NeoGenomics, as does the potent public interest in favor of life saving cancer tests that uniquely detect particular cancer types.

II. DISCUSSION

On application for a stay pending appeal pursuant to Federal Rule 62(d), a court must consider "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *see also Long v. Robinson*, 432 F.2d 977, 979 (4th Cir. 1970). These factors,

however, "cannot be reduced to a set of rigid rules," *Hilton*, 481 U.S. at 777. Thus, "[w]hen harm to applicant is great enough, a court will not require 'a strong showing' that applicant is 'likely to succeed on the merits.'" *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 513 (Fed. Cir. 1990); *see also Hilton*, 481 U.S. at 778 (stay appropriate where the applicant can "demonstrate a substantial case on the merits" if the other factors "in the traditional stay analysis militate" in favor of a stay). Thus, where there are "serious" or "substantial legal question[s]" regarding validity, infringement, or irreparable harm, a stay pending appeal may be appropriate. *Standard Havens Prods.*, 897 F.2d at 513–14. Courts in the Fourth Circuit apply this standard when addressing stay motions in patent cases. *See, e.g.*, *Par Pharms., Inc. v. TWI Pharms., Inc.*, 2014 WL 3956024, at *1 & n.1 (D. Md. Aug. 12, 2014); *MicroStrategy, Inc. v. Business Objects, S.A.*, 661 F. Supp. 2d 548, 558–59 (E.D. Va. 2009).

For the reasons set forth below, there is a strong likelihood of success on appeal for each issue where there is a substantial appeal question presented, and the likelihood is even greater that NeoGenomics will succeed on appeal on at least one of these issues.

A. There Are At Least Serious and Substantial Questions Regarding the Merits of the Order

1. There Are Serious and Substantial Questions Regarding Validity and Infringement

In an application for a preliminary injunction, "[a]n accused infringer can defeat a showing of likelihood of success on the merits by demonstrating a substantial question of

validity or infringement." *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1165 (Fed. Cir. 2014).

a) Invalidity Of The '035 Patent

There is strong evidence that the '035 Patent is invalid for obviousness and also due to a written description violation, including the thoughtful expert opinions of Professor Van Ness. Each of those defenses independently implicates substantial questions warranting a stay pending appeal.

Obviousness. In its Order, this Court acknowledged that before the priority date for the '035 Patent, the 2010 Kaper publication taught a method for sequencing and amplifying DNA that is functionally indistinguishable from the method taught in the '035 Patent. D.I. 169 at 9. The only distinction the Court drew between the claims of the '035 Patent and the prior art from Kaper was that Kaper "used DNA samples from tumor tissue, not cfDNA," and that it was "unlikely a person skilled in the art would have been motivated to use cfDNA with [the existing method] and would have anticipated success in doing so." *Id.* at 9–10.

Natera and its experts have repeatedly admitted—in fact, have affirmatively averred—that using cfDNA to monitor for diseases such as cancer using DNA sequencing techniques like those in the '035 Patent was well known to persons of skill in the art by at least November 2009. *See* D.I. 97-10 at 3; D.I. 97-20 ¶¶ 4, 25, 57–58. This Court nonetheless reasoned that "challenges associated with cfDNA, and others, presented obstacles to successfully amplifying and sequencing ctDNA with precision during the

relevant time period." D.I. 169 at 10. But Natera's own experts admit that notwithstanding these supposed "challenges," "one of ordinary skill would have expected success in being able to sequence cell-free DNA" by at least 2009, D.I. 97-12 ¶ 115; *see also* D.I. 162-1 at 16:9–24. Those concessions are consistent with examples of prior art specifically contemplating the use of "sequencing" techniques on cfDNA "for the detection of a specific cancer." D.I. 97-19 ¶ 248; *see also* D.I. 97-18. The mere fact that applying existing sequencing and amplification methods to cfDNA might be said to involve unique "challenges" does not render the '035 Patent nonobvious. *See Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 8 F.4th 1349, 1358 (Fed. Cir. 2021) (motivation to combine notwithstanding "safety and efficacy concerns"). Natera's repeated averments in other litigation that the application of existing sequencing technology to cfDNA was obvious prior to 2011 is powerful evidence that the Federal Circuit should reasonably conclude raises a substantial question of validity for the jury to consider.

Lack of Adequate Written Description. A patent must include an adequate written description that "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). One of the purposes of this requirement is to ensure that an inventor does not try to frame the claims of the patent more broadly than what the inventor actually has described as the essential elements of the patented invention. *See Arthrex, Inc. v. Smith & Nephew, Inc.*, 35 F.4th 1328, 1342–44 (Fed. Cir. 2022); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998). Relevant here, that

means an inventor may not specify a particular method in the written description, but then draft the claims to include other methods not specified in the written description. In *Arthrex*, for example, the Federal Circuit held a patent invalid because the relevant claim covered the use of "eyelets" generally, even though the written description specified that the use of a specific type of eyelet—a "fixed aperture" eyelet—was an essential component of the invention. 35 F.4th at 1342–44.

Here, the specification in the '035 Patent made clear repeatedly that an "essential" element of the claimed invention is the use of a PCR method—namely, the selection of certain primers— that "reduce[s] the formation of non-target amplicons during multiplex PCR," i.e., a method that reduces the formation of amplicons that are not relevant to and may confound analysis of the target amplicons. D.I. 1-2 at 3:4–14, 54:46–50. The '035 Patent explicitly states that "[t]he present invention *is based in part* on the *surprising discovery*" of a method for selecting primers to reduce the number of "junk" amplicons produced during PCR. *Id.* at 46:27–41; *see also id.* at 48:14–17 (a new primer selection method for reducing "junk" amplicons has "unexpectedly enabled" better PCR multiplexing).

Claim 1 of the '035 Patent, however, is not limited to the use of this purportedly "essential" PCR method, and instead purports to cover the use of *any* PCR method that "tag[s] isolated cell free DNA with one or more universal tail adaptors." D.I. 1-2 at 213. In other words, claim 1 purports to cover any *generic* PCR method, but the specification is focused on the use of a specific PCR method the inventor claimed as unique and

"essential." Where, as here, a patent's specification "specifically distinguishes the prior art as inferior and touts the advantages of" a new method or invention, the patent may cover *only* that new method or invention, "and nothing broader." *Tronzo*, 156 F.3d at 1159. The '035 Patent is therefore invalid for lack of an adequate written description to support the generic PCR method covered by claim 1.

The Court declined to consider this defect in the '035 Patent because, it said, NeoGenomics offered only a "perfunctory" explanation in a single paragraph. D.I. 169 at 11 & n.7. While NeoGenomics's brief and supporting expert declaration were sufficient to establish a substantial question, NeoGenomics explained to the Court in detail at the preliminary injunction hearing the problem with claim 1's coverage of generic PCR methods. *See* Hr'g Tr. 144:20–147:3 (Nov. 27, 2023). As counsel explained:

> If you look at the claims of the '454 patent and the '035 patent, they are generic. There are no claim limitations related to selecting primers to avoid junk. You can select the primers to avoid the junk, or you can do it without selecting the primers to avoid the junk. They've claimed generically. And you can't do that when you have a patent specification that tells you it's essential to select the primers to avoid the junk.

Id. at 146:6–13. Counsel for NeoGenomics also used multiple slides explaining this argument and evidence. *See* Defs.' Ex. 1 at 125–36. NeoGenomics's findings of fact and conclusions of law also set forth why this defense raises a substantial issue. *See* D.I. 162 ¶¶ 55–66. Both the evidence and the argument were before the Court, and the Court's rejection of this issue without further analysis raises at least a substantial appeal question.

b) Infringement Of The '035 Patent

NeoGenomics also raised substantial questions regarding whether RaDaR infringes the '035 Patent. Claim 1 of the '035 Patent requires in its first step "tagging isolated cell free DNA with one or more universal tail adaptors to generate tagged products." The next element of claim 1 is a distinct step that requires "amplifying *the tagged products* one or more times to generate final amplification products." D.I. 1-2 at 213 (emphasis added). In other words, the second step of the claim requires that one perform "targeted amplification" of the "tagged products" that were generated in the first step. There is no infringement if any claim requirement is missing. *CommScope Technologies LLC v. Dali Wireless Inc*., 10 F.4th 1289, 1298 (Fed. Cir. 2021).

The issue with respect to the '035 Patent is whether RaDaR satisfies the second claim element requiring "targeted amplification" of "tagged products." This Court held that RaDaR satisfies this element because "RaDaR first tags the products with the CS1 adaptor sequence, *then performs targeted amplification to tag the products a second time with the CS2 sequence*." D.I. 169 at 6 (emphasis added). In other words, the Court held that the introduction of the CS2 tag corresponded to *both* the "tagging" element in the first step of the claim and "targeted amplification" at second step. This ruling is erroneous and contrary to law.

As an initial matter, Natera never presented the theory adopted by the Court. In its opening brief, Natera argued generally that the introduction of the CS1 *and* CS2 throughout the pre-amplification as a whole satisfied the tagging required in the first claim

element. D.I. 17 ¶ 88. Natera never presented a coherent theory of where the claimed "targeted amplification" takes place relative to this pre-amplification. *Compare id.* ¶ 88, *with id.* ¶¶ 100–01. The first time Natera even offered its alleged theory of how RaDaR satisfies the second claim element was in its reply brief, when it argued that the "targeted amplification" required in the second claim element is actually satisfied by a subset of cycles of the pre-amplification process: "[A]t least one tag is added at the first cycle, the *dual-tagged products are formed by at least the second cycle's end*, and tagged products are *thereafter* amplified by targeted amplification numerous times in the remaining cycles of PCR." D.I. 144 at 6 (emphasis added).[1]

Both this Court's and Natera's interpretation effectively construe "tagging" and "targeted amplification" to be one and the same acts, both happening in a singular chemical process at the exact same time. That is because Natera's expert, Dr. Metzker, confirmed repeatedly that RaDaR's pre-amplification step generates "copies" that correspond to "tagged products" in *all 15 cycles* of the pre-amplification process. *See, e.g.*, D.I. 116-6 at 97:4–17, 97:21–98:12, 107:6–17, 110:5–111:12. In other words, Dr. Metzker confirmed, the entire pre-amplification process in RaDaR that Natera says performs the claimed "targeted amplification" of the "tagged products" is what creates the "tagged products" in the first instance.

[1] As Dr. Metzker confirmed, this new theory was not in his original declaration. *See, e.g.*, D.I. 116-6 at 91:20–24, 93:5–10, 94:10–95:22, 96:12–23, 98:13–99:8, 106:22–107:4.

Because there is no subsequent "targeted amplification" of the "tagged products" in the RaDaR process, Natera bewilderingly urged that some of the 15 pre-amplification cycles involved in tagging should be reclassified as "targeted amplification." The defect with this construction is that it contravenes two general rules of claim construction. First, "[w]here a claim lists elements separately, the clear implication of the claim language is that those elements are distinct components of the patented invention." *Becton, Dickinson & Co. v. Tyco Healthcare Grp.*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (quotation marks omitted); *see also Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398, 1404–05 (Fed. Cir. 1996) (separate claim elements "logically cannot be one and the same"). Second, distinct claim steps must be performed in the order written where required by the claim language as a "matter of logic or grammar." *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369 (Fed. Cir. 2003). Claim construction is typically reviewed de novo, and this is a material issue that the Federal Circuit should have the opportunity to address before RaDaR is eliminated from the market.

Here, the claims recite that the "targeted amplification" must be performed on the "tagged products" such that the "tagged products" must, as both a matter of logic and grammar, be generated prior to the "targeted amplification." *See, e.g.*, *Hytera Commc'ns Co. v. Motorola Sols.*, Inc., 841 F. App'x 210, 218 (Fed. Cir. 2021) (requiring steps to be performed in order written where each step of the method provides an antecedent basis for the steps that follow"). The "targeted amplification" must thus be performed after the *completion* of the first claim element requiring tagging. To construe the '035 Patent

otherwise would be to dissolve the distinction between the two elements and disregard the structure and plain meaning of the claim. The inconsistency between the claim construction adopted by the Court (insofar as it conducted one) and what the claim states raises a substantial appeal question.

2. There Are Serious And Substantial Questions Of Irreparable Harm

As an additional and independent ground for a stay, there are serious and substantial questions regarding the sufficiency of Natera's evidence and arguments regarding the irreparable harm Natera has claimed in this suit. Again, while NeoGenomics understands the Court ultimately found in favor of Natera on irreparable harm, the facts and argument below show that there is at least a substantial appeal question as to whether Natera carried its burden. That is enough for a stay, particularly in light of the harm to NeoGenomics in the absence of a stay pending appeal.

First, the Court legally erred in holding that the existence of head-to-head competition is sufficient on its own to establish irreparable harm. D.I. 169 at 14–15. The cases the Court cited on this point concur that direct competition is *relevant* to the issue of irreparable harm, but none hold that it is *dispositive*. *See id.* (citing *TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 793 (Fed. Cir. 2019) (direct competition paired with "lost market share tend to evidence irreparable harm"); *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013) (harm through direct competition is "often irreparable"); *Presidio Components Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012) (direct competition is "one factor" relevant to irreparable

harm)). That is because such a rule "would require a finding of irreparable harm to every manufacturer/patentee, regardless of circumstances." *Abbott Lab'ys v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006).

The Court buttressed its conclusion by asserting that "NeoGenomics is Natera's only competitor" in the "tumor informed MRD marketplace." D.I. 169 at 14. As an initial matter, Natera's CEO stated during the pendency of the motion that Natera "very, very rarely see[s] any competitors in the field today," and if it did, it typically would see Guardant Health. D.I. 93 at 3. He added it would take a long time before Natera saw competition from new entrants. *Id.* In addition, the market report relied upon by Natera's expert clearly shows that Natera is not expected to lose significant market share to NeoGenomics. *See* D.I. 921-1 at 6, 17, 19; D.I. 108-7 at 125:13–126:10. Accordingly, the Federal Circuit may reasonably conclude, and NeoGenomics believes there is a strong likelihood that it will conclude, that there is not sufficient evidence of direct competition.

And the Court's conclusion that there is a separate tumor-informed MRD marketplace is also at odds with the evidence. The market analyses in the record do not treat it as such. And Natera's own internal market analyses and its CEO confirmed that doctors do not actually express that preference in any way that is meaningful from a competition standpoint. *See* D.I. 93 at NEOGEN00018317; D.I. 111 at NAT-NEO-00729506. In fact, Natera's principal competition is from Guardant Health, a provider of tumor-naïve MRD testing, as shown throughout the record. *See, e.g.,* D.I. 93 at NEOGEN00018317. The Court's conclusion that Natera's and NeoGenomics's

products are likely the "only two" options for many oncologists simply is not supported by the record. Indeed, the Court acknowledged that "[t]here is not abundant evidence of lost sales," D.I. 169 at 16, even though RaDaR has been available to biopharmaceutical companies for several years now. The only example the Court offered was Moderna. *See id.* at 16. This overlooks that Moderna did not have interest in partnering with Natera on that project in view of the sensitivity limitations in Natera's test, as shown by the evidence. D.I. 113 ¶ 32.

Second, the Court did not disagree that an unreasonable delay in filing for preliminary injunctive relief "undercuts the urgency that forms the cornerstone of injunctive relief." *Quad/Tech, Inc. v. QI B.V.*, 701 F. Supp. 2d 644, 657 (E.D. Pa. 2010). Instead, it held there was no substantial delay here because Natera obtained the '035 Patent in December 2022, NeoGenomics entered the clinical market in March 2023, and this lawsuit was filed in July 2023. D.I. 169 at 16–17. Setting aside the fact that Natera claims its inventions embodied in the '035 Patent date back to 2011, yet failed to claim them for nearly a decade, *see* D.I. 107 at 20–21, limiting Natera's alleged harm to post-March 2023 is inconsistent with the record and Natera's own allegations.

Inivata announced biopharmaceutical deals for RaDaR as early as the spring of 2021. D.I. 112 ¶ 13. Natera has claimed irreparable harm from the completion of those contracts, *see* D.I. 122-1 at 81:20–82:3, and the Court identified "biopharmaceutical partnerships" as one of the key sources of harm here, D.I. 169 at 15. Natera's own expert admitted that by October 2022, it was already "well known" that "NeoGenomics was

commercializing the RaDaR test." D.I. 108-7 at 76:23–77:2. And Natera has conceded in its discovery responses that it believed RaDaR was infringing the '035 Patent by at least December 2022, when it sued Inivata for infringement of the '454 Patent. *See* D.I. 91-4 at 18–19. The only change in March 2023 was that NeoGenomics began selling RaDaR commercially for clinical use. *See* D.I. 94-9; D.I. 112 ¶ 15. But clinical use is just one part of the market for which Natera and NeoGenomics are competing. The fact that Natera believes it is suffering *additional* harm as of March 2023 does not explain its delay in filing suit before then when it brought suit on other patents at that same time. A short stay pending appeal is warranted.

B. NeoGenomics Will Suffer Irreparable Harm In The Absence Of A Stay

NeoGenomics will suffer irreparable harm if the preliminary injunction is not stayed pending appeal.

There is no question NeoGenomics will suffer irreparable harm from the preliminary injunction. Natera's own expert admitted as much in his deposition. *See* D.I. 108-7 at 145:1–146:2. That is unsurprising given that NeoGenomics is attempting to compete with the dominant market share leader and currently occupies only a small fraction of that market. *See Waters Corp. v. Agilent Techs. Inc.*, 410 F. Supp. 3d 702, 717 (D. Del. 2019) (recognizing harm to defendant where plaintiff controlled the market).

In its Order, the Court did not dispute this serious and irreparable harm to NeoGenomics, but minimized that harm on the grounds that "NeoGenomics is not as dependent on RaDaR's success" and "RaDaR also only recently became commercially

available." D.I. 169 at 19. But the relative size and dependency on the competing products of two firms is relevant to irreparable harm only insofar as a preliminary injunction may prevent *the enjoined* party from selling its products. *See Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1379 (Fed. Cir. 2020). Even a large company may "suffer considerable hardship absent [a stay] because it has invested [resources] to develop its products." *Id.* (discussing preliminary injunction). Indeed, just two days ago, the Federal Circuit ordered a stay of an injunction against Apple's sale of certain Apple Watches, *see Apple Inc. v. Int'l Trade Comm'n*, No. 24-1285 (Fed. Cir. Dec. 27, 2023), even though Apple is the largest company in the world by market capitalization and sells dozens of innovative and profitable products.

C. Any Harm To Natera Is Minimal

As set forth above, Natera's claims of irreparable harm cannot be reconciled with its delay in prosecuting this case or the dominant market position it currently holds. But even if the Court is not persuaded on that point, the evidence is clear that any such harm to Natera is miniscule compared to that incurred by NeoGenomics as a result of the preliminary injunction. Natera's expert acknowledged that Natera "has a dominant" and "durable" "market position." D.I. 108-7 at 24:14–25:5, 125:13–126:10. Projections about losses in Natera's market share (largely to Guardant Health) suggest a market share drop of just 7% over the next 3–5 years. D.I. 92-1 at 12. Natera's Signatera product may be "a major contributor to Natera's future success," D.I. 169, at 19, but Natera will be free to continue to market and sell Signatera with or without the preliminary injunction. That is

contrast to the case relied upon by the Court, in which the *enjoined* party was entirely dependent on the sale of the allegedly infringing products. *See Bio-Rad Labs.*, 967 F.3d at 1379. This evidence weighs in favor or a stay pending appeal and also shows a likelihood of success on appeal.

D. The Public Interest Favors A Stay

Importantly, the public interest favors a stay. In analyzing the public interest in the Order, the Court observed that "competition from an infringing product does not benefit the public." D.I. 169 at 20. This overlooks that "although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988). Under that paradigm, courts frequently find that the public interest favors broader availability of medical services and products. *See, e.g.*, *Cordis Corp. v. Boston Sci. Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004); *Novo Nordisk A/S v. Pfizer Inc.*, 2006 WL 3714312, at *6–7 (S.D.N.Y. 2006); *Conceptus, Inc. v. Hologic, Inc.*, 2012 WL 44064, at *3–4 (N.D. Cal. Jan. 9, 2012).

Numerous companies have reached out to NeoGenomics because the high sensitivity of the RaDaR assay allows it to better detect cancer in early stages. D.I. 112 ¶¶ 29–36, 44–47. The Cowen Report—on which both Natera and the Court have relied—observes that RaDaR "has a differentiated chemistry and targets up to 48 tumor-specific variants and has a sensitivity profile that can offer advantage over existing players." D.I.

92-1 at 5. This sensitivity allows researchers to enrich clinical trials by identifying patients at high risk of recurrence based on ctDNA status, which can lead to substantial reductions in trial sample size. D.I. 112 ¶ 29. Certain clinical trials require a very high level of testing sensitivity because of [redacted] and challenging test samples (*id.* ¶ 31), [redacted] (*id.* ¶¶ 32–33), [redacted] (*id.* ¶ 36), or the need [redacted] (*id.* ¶ 39); these clinical tests would not be possible with Natera's Signatera. *Id.* ¶¶ 29–39, 43. The use of ctDNA has great potential to significantly reduce trial duration and cost, ultimately leading to the expedited approval of new therapies. *Id.* ¶ 47. If planned clinical trials using the RaDaR assay are enjoined, countless cancer patients will be deprived of therapies that could have been developed through these clinical trials. Importantly, NeoGenomics has a pending application for Medicare reimbursement for lung and other cancer indications, while Natera was forced to admit at the hearing that it has not even applied for those. *See* Hr'g Tr. 214:12–21 (Nov. 27, 2023). Signatera also has been criticized for its accuracy, including its rate of false positives. *See* D.I. 112 ¶ 41.

Enjoining the continued use of RaDaR would therefore deprive cancer patients and scientists in need of highly sensitive cancer tests for access to such tests, a result that is not in the public interest. With a higher sensitivity profile, RaDaR has a better chance than Signatera of detecting cancerous cfDNA in patients. A stay would thus allow cancer patients access to a more accurate assay than what Natera is able to offer, whereas a continued injunction would put patients at a higher risk that cancerous cfDNA goes

undetected. In addition to independently supporting a stay, these facts are likely to persuade the Federal Circuit that the preliminary injunction is not in the public interest.

III. CONCLUSION

For the foregoing reasons, NeoGenomics respectfully requests that the Court stay the injunction pending resolution of the appeal.

This the 29th day of December 2023

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CERTIFICATE OF WORD COUNT

The undersigned counsel hereby certifies that this brief complies with the word count limitations of Local Rule 7.3(d).

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CERTIFICATE OF SERVICE

I hereby certify that on December 29, 2023, I electronically filed the foregoing **DEFENDANT NEOGENOMICS LABORATORIES, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO STAY** with the Clerk of Court using the CM/ECF system.

Dated: December 29, 2023

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